

b) a nucleic acid molecule which encodes a polypeptide comprising the amino acid sequence of SEQ ID NO:7.

247. (Amended) A host cell which contains the nucleic acid molecule of claim 245.

254. (Amended) A method for producing a polypeptide, comprising culturing the host cell of claim 247 under conditions in which the nucleic acid molecule is expressed.

255. (Amended) The method of claim 254 wherein said polypeptide comprises the amino acid sequence of SEQ ID NO:7.

REMARKS

Status of the Claims

Claims 250-253 and 256-268 have been canceled without prejudice to or disclaimer of the subject matter therein, responsive to the restriction requirement. Claims 243-244, 247, and 254-255 have been amended. Support for these amendments is found in the specification as described below in the response. Therefore, no new matter has been added by amendment. Claims 243-249, and 254-255 are now pending. ✓

Claims 243-244, 254-255 have been amended to remove non-elected material. Claim 247 has been amended to depend on claim 245, not 243, thereby directing it to subject matter that is not a product of nature. Claim 254 has been amended to become dependent on claim 243.

The Examiner's comments are addressed below in the order set forth in the Office Action.

Objections to the Specification

The specification has been objected to because ATCC accession number is left blank. ✓
The specification has been amended to remove these blanks, thereby obviating the objection.

Claim Objections

Claims 243-249 and 254-255 have been objected to for being drawn to non-elected products. The claims have been amended to remove non-elected matter, thereby obviating the objection.

The Rejections of the Claims under 35 U.S.C. § 101 Should Be Withdrawn

Claims 247-248 have been rejected under 35 U.S.C. § 101 as drawn to naturally occurring subject matter. The rejection is respectfully traversed.

Claim 247 has been amended to be dependent upon claim 245 instead of claim 243, thereby obviating the rejection. Applicants respectfully request that the rejection be withdrawn.

The Rejection Under 35 U.S.C. § 112, First Paragraph, Should be Withdrawn

The Examiner has rejected 243-249 and 254-255 under 35 U.S.C. § 112, first paragraph, written description. This rejection is respectfully traversed.

The Examiner states that the specification fails to describe common attributes of the genus. However, claim 243 as amended, is drawn only to “an isolated nucleic acid molecule selected from the group consisting of: a) a nucleic acid molecule comprising a nucleotide sequence which is at least 91% identical to the nucleotide sequence of SEQ ID NO:8, or a complement thereof; and, b) a nucleic acid molecule which encodes a polypeptide which is at least 91% identical to the amino acid sequence of SEQ ID NO:7, wherein the nucleic acid molecule encodes a polypeptide with sulfatase activity.” Support for these amendments can be found, for example, in the specification on page 17, lines 26-29, where percent identities are recited, and on page 1, line 3, where it is stated that the polypeptides of the invention are sulfatases. Furthermore, biological activity of sulfatases is described, for example, on page 4, lines 14-16.

Figure 16 shows a hydrophobicity plot of sulfatase 26212, with an indication that a PFAM analysis concluded that the sequence was a sulfatase. In addition, Figure 18 shows an analysis of the 26212 sulfatase open reading frame for amino acids corresponding to specific functional sites. In this analysis, sulfatase signature sites are indicated. One of skill in the art

would recognize that these sites would be less likely to tolerate mutation and could therefore perform mutagenic activities accordingly. The specification, on page 5, lines 12-15, states that a “high degree of similarity occurs particularly in the amino terminal region which contains accordingly a potential consensus sulfatase signature”, further providing structural information pertaining to the sulfatase family. Claim 243 has also been amended to require that the nucleic acid sequences and polypeptide sequences encode polypeptides with sulfatase activity.

Claim 244 has been amended to become an independent claim directed to isolated nucleic acid molecules comprising the nucleotide sequence of SEQ ID NO:8, nucleic acid molecules which encode polypeptides comprising the amino acid sequence of SEQ ID NO:7, wherein the nucleic acid molecules encode polypeptides having sulfatase activity. Support for these amendments can be found in the original claims, and throughout the specification, for example, on page 11, lines 25-29.

For all of these reasons, one of skill in the art would recognize that applicants were in possession of the claimed invention. Accordingly, Applicants respectfully request that the rejection of claims 243-249 and 254-255 be withdrawn.

Claims 243-249 and 254-255 are rejected under 35 U.S.C. 112, first paragraph, as nonenabled. This rejection is respectfully traversed.

Claims 243 and 244 have been amended as stated above. Claim 243 has been amended to require that the sequences encode polypeptides with sulfatase activity, for which the specification provides enablement. The claims now encompass molecules having a high structural similarity to SEQ ID NO:8, and which exhibit sulfatase activity. As mentioned above, the specification provides guidance about the structural requirements of a sulfatase, and therefore, one of skill in the art would recognize positions within a protein’s sequence that are required for activity, as well as areas that are more variable and could be modified successfully. Guidance regarding conservative substitutions of amino acids has been provided (see Table 1 on page 20, and page 21, lines 5-8, where direction is given concerning the production of fully functional variants).

Finally, the specification provides guidance regarding sulfatase activity on page 4, lines 14-16. As noted on page 22, lines 18-20, activity can be monitored by assaying for peptide bond hydrolysis. In addition, techniques for measuring sulfatase activity are well known in the art. Accordingly, one of skill in the art would be able to determine the functionality of sulfatase variants.

Thus, a rational scheme for determining the regions of the recited sulfatase that would tolerate modification has been provided. Based on the guidance regarding domains of 26212 that are conserved between all sulfatases, and the methods for identifying additional residues critical for sulfatase function, the skilled artisan could choose among possible modifications to produce polypeptides within the parameters set forth in the claims and then test these modified variants to determine if they retain sulfatase activity. Although some quantity of experimentation would be required, the level of experimentation would not be undue in view of the amount of direction provided in the specification, the state of the prior art, and the level of skill of one of ordinary skill in the art. These factors all favor a conclusion that one of skill in the art could practice the claimed invention without undue experimentation. Therefore, the rejection of the claims under 35 U.S.C. 112, first paragraph, should be withdrawn.

Claims 243-249 and 254-255 are rejected under 35 U.S.C. 112, first paragraph, as nonenabled. This rejection is respectfully traversed.

The claims have been amended to remove all reference to plasmids deposited with ATCC, thereby obviating the rejection.

Claims 243-249 and 254-255 have been rejected as indefinite. This rejection is respectfully traversed.

The claims have been amended to remove all reference to plasmids deposited with ATCC, thereby obviating the rejection.

Claims 243-249 and 254-255 have been rejected as indefinite, with respect to the hybridization language. This rejection is respectfully traversed.

The claims have been amended to remove all reference to hybridization language, thereby obviating the rejection.

The Rejections of the Claims under 35 U.S.C. § 102(a) Should Be Withdrawn

Claims 243-249 and 254-255 are rejected under 35 U.S.C. § 102(a) as being anticipated by Peters *et al.* These rejections are respectfully traversed.

The Examiner submits that Peters *et al.* teaches a nucleic acid molecule that is at least 45% identical to SEQ ID NO:8 (no alignment was provided). The claims have been amended to require at least 91% identity with SEQ ID NOS:7 or 8, thereby alleviating the concerns of the Examiner. Therefore, the rejection should be withdrawn.

Claims 243-249 and 254-255 are rejected under 35 U.S.C. § 102(a) as being anticipated by Wood *et al.* These rejections are respectfully traversed.

The claims have been amended to recite an identity requirement of 91% to SEQ ID NOS:7 or 8. Therefore, Wood *et al.* does not anticipate the claims of the instant invention, and the rejection of the claims under 35 U.S.C. § 102(a) should be withdrawn.

CONCLUSION

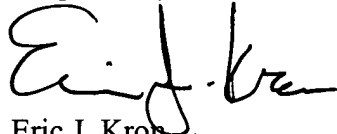
In view of the above amendments and remarks, Applicants submit that the rejection of the claims is overcome. Applicants respectfully submit that this application is now in condition for allowance. Early notice to this effect is solicited. If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject Application, the Examiner is invited to call the undersigned.

It is noted that an initialed copy of the PTO Form 1449 that was submitted with Applicants' Information Disclosure Statement filed June 12, 2002, has not been returned to Applicants' representative with the Office Action. Accordingly, it is requested that an initialed copy of the Form 1449 be forwarded to the undersigned with the next communication from the PTO. In order to facilitate review of the references by the Examiner, copies of the Information

Disclosure Statement and the Form 1449 are attached hereto. Copies of the cited references were provided at the time of filling the original Information Disclosure Statement, and, therefore, no additional copies of the references are submitted herewith. Applicants will be pleased to provide additional copies of the references upon the Examiner's request if it proves difficult to locate the original references.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

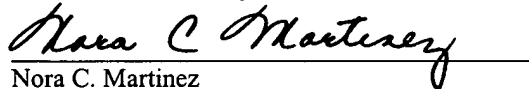


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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231, on January 23, 2003.


Nora C. Martinez

Version with Markings to Show Changes Made:

In The Specification:

Please amend the paragraph beginning on page 6, line 4, to read as follows:

Novel sulfatase nucleotide sequences, and the deduced sulfatase polypeptides are described herein. Accordingly, the invention provides isolated sulfatase nucleic acid molecules having the sequences shown in SEQ ID NOS:2, 4, 6, and 8 or in the cDNA deposited [as ATCC Nos. _____ on _____, respectively] with ATCC as Patent Deposit Number PTA-1639 (which corresponds with SEQ ID NO:4), or PTA-1846 (which corresponds with SEQ ID NO:6) ("the deposited cDNA"), and variants and fragments thereof.

Please amend the paragraph beginning on page 11, line 13, to read as follows:

Plasmids containing the sulfatase cDNA inserts were deposited with the Patent Depository of the American Type Culture Collection (ATCC), 10801 University Boulevard, Manassas, Virginia, on [_____,] April 5, 2000 or May 9, 2000 and assigned Patent Deposit Numbers [_____] PTA-1639 or PTA-1846, respectively. The deposits will be maintained under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. The deposits were made merely as a convenience for those of skill in the art and is not an admission that a deposit is required under 35 U.S.C. § 112.

Please amend the paragraph beginning on page 15, line 28, to read as follows:

The invention relates to novel sulfatases, having the deduced amino acid sequence shown in Figures 1, 5, 10, and 15 (SEQ ID NOS:1, 3, 5, and 7) or having the amino acid sequences encoded by the deposited cDNAs, [ATCC Nos. _____] Patent Deposit Numbers PTA-1639 or PTA-1846. The deposited sequences, as well as the polypeptides encoded by the sequences, are incorporated herein by reference and control in the event of any conflict, such as a sequencing error, with description in this application.

In The Claims:

Please amend claims 243-244, 247, and 254-255 as follows:

243. (Amended) An isolated nucleic acid molecule selected from the group consisting of:

a) a nucleic acid molecule comprising a nucleotide sequence which is at least [45%]91% identical to the nucleotide sequence of SEQ ID NO:[2, 4, 6, or] 8, [the cDNA insert of any of the plasmids deposited with ATCC as Patent Deposit Numbers ____, ____, ____, or ____,] or a complement thereof; and,

b) [a nucleic acid molecule comprising a fragment of at least 15 nucleotides of the nucleotide sequence of SEQ ID NO:2, 4, 6, or 8, the cDNA insert of any of the plasmids deposited with ATCC as Patent Deposit Numbers ____, ____, ____, or ____, or a complement thereof;

c)] a nucleic acid molecule which encodes a polypeptide [comprising]which is at least 91% identical to the amino acid sequence of SEQ ID NO:[1, 3, 5, or]7, [or an amino acid sequence encoded by the cDNA insert of any of the plasmids deposited with ATCC as Patent Deposit Numbers ____, ____, ____, or ____;

d) a nucleic acid molecule which encodes a fragment of a polypeptide comprising the amino acid sequence of SEQ ID NO:1, 3, 5, or 7, or an amino acid sequence encoded by the cDNA insert of any of the plasmids deposited with ATCC as Patent Deposit Numbers ____, ____, ____, or ____, wherein the fragment comprises at least 12 contiguous amino acids of SEQ ID NO:1, 3, 5, or 7, or an amino acid sequence encoded by the cDNA insert of any of the plasmids deposited with ATCC as Patent Deposit Numbers ____, ____, ____, or ____; and

e) a nucleic acid molecule which encodes a naturally occurring allelic variant of a polypeptide comprising the amino acid sequence of SEQ ID NO:1, 3, 5, or 7, or an amino acid sequence encoded by the cDNA insert of any of the plasmids deposited with ATCC as

Patent Deposit Numbers _____, _____, _____, or _____, wherein the nucleic acid molecule hybridizes to a nucleic acid molecule comprising SEQ ID NO:2, 4, 6, or 8, or a complement thereof under stringent conditions] wherein the nucleic acid molecule encodes a polypeptide with sulfatase activity.

244. (Amended) [The] An isolated nucleic acid molecule [of claim 243, which is] selected from the group consisting of:

a) a nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:[2, 4, 6, or]8, [the cDNA insert of any one the plasmids deposited with ATCC as Patent Deposit Numbers _____, _____, _____, or _____,]or a complement thereof; and

b) a nucleic acid molecule which encodes a polypeptide comprising the amino acid sequence of SEQ ID NO:[1, 3, 5, or]7[, or an amino acid sequence encoded by the cDNA insert of any of the plasmids deposited with ATCC as Patent Deposit Numbers _____, _____, _____, or _____].

247. (Amended) A host cell which contains the nucleic acid molecule of claim [243]245.

254. (Amended) A method for producing a polypeptide [selected from the group consisting of:

a) a polypeptide comprising the amino acid sequence of SEQ ID NO:1, 3, 5, or 7, or an amino acid sequence encoded by the cDNA insert of any of the plasmids deposited with ATCC as Patent Deposit Numbers _____, _____, _____, or _____;

b) a polypeptide comprising a fragment of the amino acid sequence of SEQ ID NO:1, 3, 5, or 7, or an amino acid sequence encoded by the cDNA insert of any of the plasmids deposited with ATCC as Patent Deposit Numbers _____, _____, _____, or _____, wherein the fragment comprises at least 12 contiguous amino acids of SEQ ID NO:1, 3, 5, or 7,



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or an amino acid sequence encoded by the cDNA insert of any of the plasmids deposited with ATCC as Patent Deposit Numbers ____, ____, ____, or ____; and

c) a naturally occurring allelic variant of a polypeptide comprising the amino acid sequence of SEQ ID NO:1, 3, 5, or 7, or an amino acid sequence encoded by the cDNA insert of any of the plasmids deposited with ATCC as Patent Deposit Numbers ____, ____, ____, or ____, wherein the polypeptide is encoded by a nucleic acid molecule which hybridizes to a nucleic acid molecule comprising SEQ ID NO:2, 4, 6, or 8, or a complement thereof under stringent conditions;]comprising culturing the host cell of claim 247 under conditions in which the nucleic acid molecule is expressed.

255. (Amended) The method of claim [252] 254 wherein said polypeptide comprises the amino acid sequence of SEQ ID NO:[1, 3, 5, or] 7.

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